PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 16647WO17815	**FOR FURTHER ACTION**	See Form PCT/IPEA/416
International application No. PCT/IL2004/000960	International filing date *(day/month/year)* 21.10.2004	Priority date *(day/month/year)* 22.10.2003

International Patent Classification (IPC) or national classification and IPC
A23L1/29, A23D9/00, C11C3/08, A23C11/04, A23L1/30

Applicant
ENZYMOTEC LTD.

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 8 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☒ *sent to the applicant and to the International Bureau)* a total of 3 sheets, as follows:
      ☒ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:
   - ☒ Box No. I Basis of the opinion
   - ☐ Box No. II Priority
   - ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - ☐ Box No. IV Lack of unity of invention
   - ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - ☐ Box No. VI Certain documents cited
   - ☐ Box No. VII Certain defects in the international application
   - ☐ Box No. VIII Certain observations on the international application

Date of submission of the demand	Date of completion of this report
24.07.2005	21.12.2005
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Groh, B Telephone No. +49 89 2399-7855

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3 and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4)
   - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

   Description, Pages

   1-26 as originally filed

   Claims, Numbers

   1-15 received on 27.07.2005 with letter of 25.07.2005

   ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	3,6-13,15
	No:	Claims	1,2,4,5,14
Inventive step (IS)	Yes:	Claims	3,6-13,15
	No:	Claims	1,2,4,5,14
Industrial applicability (IA)	Yes:	Claims	1-15
	No:	Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Re Item V

Reference is made to the following documents:

D1: EP-A2-0 882 797 (UNILEVER N.V; UNILEVER PLC; LODERS CROKLAAN B.V) 9 December 1998 (1998-12-09)
D2: EP-A1-0 965 578 (SUNTORY LIMITED) 22 December 1999 (1999-12-22)
D3: DATABASE MEDLINE [Online] US NATIONAL LIBRARY OF MEDICINE (NLM), BETHESDA, MD, US; November 1997 (1997-11), LUCAS A ET AL: "Randomised controlled trial of a synthetic triglyceride milk formula for preterm infants." XP002315783 Database accession no. NLM9462186
D4: US-A-4 876 107 (KING ET AL) 24 October 1989 (1989-10-24)
D5: US-A-3 542 560 (RUDOLPH M. TOMARELLI et al) 24 Nov. 1970 (1970-11-24)
D6: DATABASE FSTA [Online] INTERNATIONAL FOOD INFORMATION SERVICE (IFIS), FRANkFURT-MAIN, DE; 1996, ANONYMOUS: "Betapol, a breakthrough in infant formula fats." XP002315801 Database accession no. 96-1-08-n0030

1 Amendments

The amendments appear to meet the requirements of Art. 41(2) PCT.

2 Novelty (Art. 33(2) PCT)

In view of the applicant's reply to the written opinion of the ISA, the following is noted:

A. Claims 1 to 6 relate to a "fat base composition". It is noted that said expression is not defined in the application as filed. It is stated in the application that "the present invention describes novel fat compositions which are components in the preparation of fat blends and infant formulas ..." (see p. 1, first paragraph).

If it was the intention of the applicant to have the present application limited to fat concentrates, then said feature would have been an essential feature, which

consequently must have had been part of the claims.

Since that is not the case, the expression "fat base composition" is **not** limited to fat compositions, which must be diluted, blended etc. before use.
Any fat composition, which is suitable to be a component in the preparation of fat blends and infant formulas in the filed of infant nutritional foods will be considered relevant during the examination of the present application.

B. The feature in the claims "mixture of (...triglycerides)" is not further specified in the application. As long as more than one type of triglyceride is present, even in a small amount, the requirement of "mixture of (...triglycerides)" is fulfilled.

1.1 Novelty over D1

Enzymatically prepared 1,3-oleic,2-palmitic-triglycerides (OPO-triglyceride) are known in the art.
D1 discloses enzymatically prepared OPO-triglycerides, for example as human milk fat replacers (see page 2, lines 2-3, page 3, lines 2-8, example 4 and claim 1 of D1). The OPO-triglycerides are prepared form vegetable sources.

Even though purification steps are mentioned in D1, the OPO-triglycerides are produced by enzymatic treatment, which never leads to pure products (here: 100% OPO-triglyceride).
Therefore, the fat composition resulting from the process disclosed in D1 is understood to be a fat composition comprising a mixture of triglycerides, which meet the requirements of present claims 1, 2 and 14

Present claims 1, 2, 4, 5 and 14 are not new over D1.

1.2 Novelty in view of D3 (Betapol^{TM})

The previous objection is dropped, because the fat composition Betapol^{TM} appears

(according to D3) not to contain at least 60% (w/w) of palmitic acid residues at the sn-2 position.

2 Inventive step (Art. 33(3) PCT)

2.1 In view of D2

D2 is about a novel triglyceride composition, used for example in formula for premature infants and term infants, or added to milk, or blended with other oils or fats (see par. [0040]).
The lipid composition of example 4 in D2 comprises 34% palmitic acid (C16:0), which is located to 96% in the position 2 of the triglyceride (see Table 1). Linoleic acid (C16:2) is present at 15%, in a ratio of 22 : 1 (= essentially all) at the positions 1,3 of the triglycerides. The triglyceride blend is produced by esterification.

The only difference to the present application is that D2 does not specify if the source of the triglycerides is vegetable or non-vegetable.

The selection of vegetable lipids (over non-vegetable lipids) for the production of the triglycerides in D2 is considered a selection among limited alternatives, which is not sufficient to provide an inventive step over the prior art, especially since no unexpected effect has been shown, which derives from the specific choice of vegetable ingredients.

The applicant's argumentation was considered. The examiner refers to the above notes A and B. The examiner further issues the opinion that, -independently to how closely a match the fat composition of D2 to the human breast milk fat is-, the triglyceride composition of D2 is suitable for infant nutritional foods (see also D2, claim 8). The examiner maintains the objection issued in the written opinion:

Claims 1, 2 and 14 do not involve an inventive step over D2.

2.2 In view of D4

The applicant's argumentation was considered. The examiner refers to the above notes A and B.

Prior art D4 discloses a substitute (human) milk fat composition for feeding young infants. The total amount of palmitic acid (see Table 3 and claim 1) is less than 33%. The amount of palmitic acid in the 2-position is more than 50%, for the blends number 1 and 4, it is 57 %.

There is no unexpected effect apparent from the small increase of the amount of palmitic acid in the 2-position of the triglycerides from 57 to 60%.

The examiner maintains the objection issued in the written opinion:
Claims 1, 2 and 14 do not involve an inventive step over D4.

2.3 Inventive step of claim 3 and related claims

There is no indication in the prior art for a substitute human milk fat composition, produced by combining an enzymatically prepared fat base as defined in claim 1 characterized in that the fatty acid moieties at the sn-2 position are between 60 and 70% (w/w).

Claim 3, and the claims depending thereof are found to involve an inventive step.

2.4 Inventive step of claim 7 and related claims

Substitute human milk fat compositions per se are known in the are (see search report). It is also known in the art to blend or add lipids with special triglyceride pattern to traditional food. See, for example claim 1 of D5, where a fat with a high content of beta-palmitic acid is blended with a milk product, in order to obtain a product, wherein the lipids resemble human milk fat.

However, there is no indication in the prior art for a substitute human milk fat composition, produced by combining an enzymatically prepared fat base as defined in claim 1 with at least one vegetable oil in the ratio defined in claim 7.

Claim 7, and the depending claims thereof are found to involve an inventive step.

3 Clarity (Art. 6 PCT)

3.1 Claims 5 and 6 are related to all previous claims, and further defined by reference to "said unsaturated fatty acid moieties". Claims 1 through 3, however, do not have any reference to unsaturated fatty acid moieties.

3.2 Claim 11 refers in the last line of the claim to a step d), which is not present (anymore).

3.3 Claim 12 refers to a step e), which is not present (anymore).

Claims:

1. An enzymatically prepared fat base composition comprising a mixture of vegetable-derived triglycerides, characterized in that:
the total palmitic acid residues content is at most 38%w/w of the total fatty acid residues;
at least 60%w/w of the fatty acid moieties at the *sn*-2 position of the glycerol backbone are palmitic acid residues.

2. The fat base composition of claim 1, wherein at least 62%w/w of the total palmitic acid residues are at the *sn*-2 position of the glycerol backbone.

3. The fat composition of claim 1 or claim 2, wherein up to 70%w/w of the total palmitic acid moieties are at the *sn*-2 position of the glycerol moiety.

~~3~~4. The fat base composition of any one of claims 1 to ~~2~~3, wherein at least 70%w/w of the fatty acid moieties at the *sn*-1 and *sn*-3 positions of the glycerol backbone are oleic acid and other unsaturated fatty acid moieties.

~~4~~5. The fat base composition of any one of claims 1 to ~~3~~4, wherein at least 40%w/w, preferably 40-60%w/w, of said unsaturated fatty acid moieties at the *sn*-1 and *sn*-3 positions are oleic acid moieties.

~~5~~6. The fat base composition of any one of claims 1 to ~~4~~5, wherein at least 6%w/w, preferably 6-17%w/w, of said unsaturated fatty acid moieties at the *sn*-1 and *sn*-3 positions are linoleic acid moieties.

~~6~~7. A substitute human milk fat composition comprising a blend of at least 25% of the fat base composition of any one of claims 1 to ~~5~~6 with up to 75% of at least one vegetable oil.

1415. Use of the fat composition of any one of claims 67 and 78 in the preparation of an infant formula.